UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 02419 Docket No. 1:13-md-2419-RWZ
This document relates to: Handy v. Box Hill Surgery Center, LLC, et al. No: 1:14-cv-14019-RWZ Armetta v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14022-RWZ Torbeck v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14023-RWZ Kashi v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14026-RWZ Bowman v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14028-RWZ Dreisch v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14029-RWZ Davis v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14033-RWZ Farthing v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14036-RWZ	**Stipulation with Consent from Plaintiffs' Counsel to Permit Dispositive Memorandum In Excess of Thirty (30) Pages Pursuant to MDL Standing Order No. 11 Filed on 1/13/15**

DEFENDANTS BOX HILL SURGERY CENTER, LLC, RITU T. BHAMBHANI, M.D., AND RITU T. BHAMBHANI, M.D., LLC'S CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS

Defendants, Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C. (hereinafter, collectively "Box Hill Defendants"), by undersigned counsel, submit this consolidated memorandum of law in support of their respective Motions to Dismiss as to *Handy v. Box Hill Surgery Center, LLC, et al.* No: 1:14-cv-14019-RWZ; *Armetta*

v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14022-RWZ; *Torbeck v. Box Hill Surgery Center, LLC, et al.* No. 1:14-cv-14023-RWZ; *Kashi v. Box Hill Surgery Center, LLC, et al.* No. 1:14-cv-14026-RWZ; *Bowman v. Box Hill Surgery Center, LLC, et al.* No. 1:14-cv-14028-RWZ; *Dreisch v. Box Hill Surgery Center, LLC, et al.* No. 1:14-cv-14029-RWZ; *Davis v. Box Hill Surgery Center, LLC, et al.* No. 1:14-cv-14033-RWZ; and *Farthing v. Box Hill Surgery Center, LLC, et al.* No. 1:14-cv-14036-RWZ (cumulatively, hereinafter "Plaintiffs," "related Plaintiffs," "instant actions," "above cases," or "related cases").[1]

I. INTRODUCTION

These eight actions are among many in this MDL arising out of the administration of a steroid—preservative free methylprednisolone acetate (hereinafter "MPA")—manufactured and sold by New England Compounding Pharmacy, Inc. a/k/a New England Compounding Center (hereinafter "NECC"). It is alleged that as a result of negligent manufacturing, cleaning and sterilization practices by NECC, as well as improper testing and "clean-room" design, that certain vials or batches of MPA became contaminated with fungus that ultimately caused harm or injury to patients, who received the MPA from their health care providers after purchasing the medication from NECC.[2] It is alleged that the tainted vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102012@51 (BUD 2/6/2013).[3]

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[1] Harry Roth, Esquire, and Michael Coren, Esquire are Plaintiffs' counsel of record in the *Handy* case (No: 1:14-cv-14019-RWZ). Patricia Kasputys, Esquire and Sharon Houston, Esquire are Plaintiffs' counsel of record in the remaining seven cases captioned above.

[2] By way of thorough background, a recent criminal indictment was filed against more than ten owners/employees of NECC asserting a host of criminal complaints such as fraud and misrepresentation, as well as deliberate acts that contributed to the contamination of the MPA through no fault of the Box Hill Defendants or other health care provider defendants in the MDL.

[3] The Lot number denotes the date of the lot's manufacture or compounding. The "BUD" is a "Beyond Use Date," which identifies the point after which a drug should no longer be used. A recent indictment of NECC owners and employees described actions whereby NECC owners and employees fraudulently labeled vials of MPA to indicate a later, incorrect BUD or to suggest that the drugs had been properly tested and were not contaminated.

The MPA in these lots was shipped to health care providers, who administered the drugs to patients, before it was discovered that the lots were contaminated. These lots were recalled by NECC under pressure from the CDC on or about September 26, 2012, after numerous patients fell ill, and some died, after contracting fungal meningitis. Litigation ensued and along with NECC and various other defendants, the Box Hill Defendants were named as defendants. The litigation was consolidated through the Judicial Panel on Multi District Litigation in the District Court of Massachusetts before the Honorable Rya Zobel. As more fully set forth below, the Box Hill Defendants are entitled to dismissal of the Complaints for failure to state a claim upon which relief can be granted.

II. STATEMENT OF THE CASES AND PROCEDURAL HISTORY

These actions involve epidural steroid injections administered by Defendant Dr. Bhambhani to eight patients (cumulatively, hereinafter "patients" or "Plaintiff patients") on various occasions in the Summer of 2012.[4] The specific facts of each individual case are not significant for the analysis provided herein. However, each of the patients in the instant actions who were treated by Dr. Bhambhani presented, in most cases, as a referral from another physician, with some sort of back or neck pain. Dr. Bhambhani examined each patient, made a diagnosis, and recommended a variety of treatments, including an epidural steroid injection. Informed consent was obtained and the patient received one or more injections of preservative-free MPA obtained from NECC.[5] These drugs were later determined to be from one of three contaminated lots as identified by the CDC. Immediately after she was notified, Dr. Bhambhani stopped using any of those drugs and quarantined them before sending the unused vials back as

[4] The patients were Brenda Rozek (deceased), John Millhausen (deceased), Linda Torbeck, Bahman Kashi (deceased), Edna Young (deceased), Belinda Dreisch, Teresa Davis, and Angela Farthing.

[5] In some instances, the patients had had previous epidural steroid injections either from Dr. Bhambhani or other physicians, and in some cases those patients had previously received MPA purchased from NECC without complication.

part of the recall. The Complaint for each action identifies the dates of treatment, including injection dates, and what followed in terms of alleged illness, injury, and/or death. (*See generally,* Complaints for each action, ranging from ¶¶ 198-223.) Some of these patients continued to be treated by Dr. Bhambhani and some even sought and received additional epidural steroid injections.

The instant Plaintiffs' claims against the Box Hill Defendants are governed by Maryland's Health Care Malpractice Claims Act (hereinafter "HCMCA" or "Act"), codified in Md. Code, Cts. & Jud. Proc. Art., 3-2A-01, *et seq*. The Act establishes requirements that must be satisfied in order for a plaintiff to proceed with an action against a Maryland health care provider for claims involving medical care. This includes, but is not limited to, first filing a Statement of Claim in the Maryland Health Care Alternative Dispute Resolution Office ("HCADRO"), filing a Certificate of Qualified Expert and a Report by a physician in the same or a similar specialty as the Defendant health care provider attesting to the merits of the case, and then filing a waiver of arbitration, before filing a Complaint in any Maryland state or any federal court.

All eight actions were initially filed in the HCADRO, pursuant to the HCMCA, accompanied by a Certificate of Qualified Expert and Report signed by Lloyd Saberski, M.D. Plaintiffs then waived arbitration and filed each action in the Circuit Court for Baltimore County, Maryland against the Box Hill Defendants, as well as other NECC affiliated individuals or entities and other non-NECC entities.[6] The Box Hill Defendants sought dismissal and/or to

[6] The other defendants added to the *Handy* action were Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn A. Chin, Ameridose, LLC, GDC Properties Management, LLC, Medical Sales Management, Inc. ("MSM"), Medical Sales Management SW, Inc. ("MSMSW"), ARL Bio Pharma, Inc., Liberty Industries, Inc., and UniFirst Corporation. Ameridose, GDC, MSM and MSMSW were the NECC-related corporate defendants responsible for actually manufacturing, marketing, selling, and/or distributing the contaminated products in question. The individual co-defendants are owners, pharmacists, and/or managers of NECC, Ameridose, GDC, MSM and MSMSW. Liberty is an outside company responsible for designing and building the supposedly sterile "clean room" where these products were manufactured. UniFirst is an outside company, which is alleged to have been responsible for cleaning the clean room where the drugs were manufactured. ARL Bio Pharma, Inc. was retained by NECC and Ameridose to provide sterility testing of the drugs at issue. In the other seven actions

transfer venue to the Circuit Court for Harford County, Maryland, but that was stayed after co-defendant Ameridose had all eight actions removed to the U.S. District Court for the District of Maryland. Pursuant to a Conditional Transfer Order (1:13-md-2419, Doc. 1507), all actions were then transferred to this MDL docket for In re: New England Compounding Pharmacy, Inc., Products Liability Litigation, which is what has prompted the Motions to Dismiss underlying this Memorandum of Law. Plaintiffs assented to a motion for extension of time to file this responsive pleading. (1:13-md-2419, Doc. 1542.)

The claims against the NECC-related defendants center on negligent manufacturing and sterility practices, including as to the maintenance of the "clean room," which led to the medication being exposed or contaminated by fungus. A global settlement fund was established and many of those entities reached settlements. Desperate for more pockets, however, the Plaintiffs' Steering Committee has guided plaintiffs to bring claims against any health care provider or clinic, including the Box Hill Defendants, who purchased the medication from NECC and administered it to any patient. The crux of the claims against all health care provider defendants is that such health care providers and clinics had a duty of "due diligence" to investigate NECC before purchasing the MPA. The other main claim is that certain state regulations required individual patient prescriptions for the purchase of such compounding medications. Plaintiffs, however, do not stop there. Grasping at straws, they also assert an "agency" relationship between the health care provider defendants and NECC and seek to impose inapplicable product liability law, as well as civil conspiracy law to the claims against health care provider defendants, including the Box Hill Defendants. It is undisputed that the health care providers and clinics, including the Box Hill Defendants, played no role in the

addressed in this Motion, Plaintiffs only added Ameridose, LLC, and UniFirst Corporation as defendants in addition to the moving Defendants.

manufacturing or sterility practices of NECC and had no knowledge of any contamination of the drug until after the recall. The Box Hill Defendants simply administered MPA to their patients.

Now that the above actions against the Box Hill Defendants are part of this MDL, the Box Hill Defendants move to dismiss the Plaintiffs' claims according to F.R.C.P. 12(b)(6) for failing to state a claim upon which relief can be granted.

III. STANDARD OF REVIEW

Rule 12(b)(6) of the Federal Rules of Civil Procedure governs motions to dismiss for failure to state a claim upon which relief can be granted. Although the Court must assume the truth of all well-pleaded facts, *Rando v. CVS Pharmacy, Inc.*, No. 12-11130-FDS, 2013 WL 6489947, at *2 (D. Mass. Dec 9, 2013), to survive a motion to dismiss plaintiffs must allege facts that "raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A Complaint must contain sufficient factual matter, if accepted as true, that is "plausible on its face." *Id.* at 570. This standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 556. A pleading that merely offers "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" is insufficient. *Id.* at 555 (emphasis added). Further, the Court need not accept as true a plaintiff's bald assertions or legal conclusions couched as facts. *Id.* Dismissal is appropriate if a plaintiff's well-pleaded facts do not "possess enough heft to show that plaintiff is entitled to relief." *Ruiz Rivera v. Pfizer Pharmaceuticals, LLC*, 521 F.3d 76, 84 (1st Cir. 2008) (quotations and original alterations omitted).

IV. LEGAL ARGUMENT

Upon information and belief, when the above actions were transferred to this MDL, Plaintiffs did not adopt the Master Complaint, nor did they utilize a "Short Form." The Box Hill Defendants only have the original Complaints filed in the Circuit Court for Baltimore County,

Maryland. The same basic claims were made in each action by the Plaintiffs against the Box Hill Defendants. As such, the claims made therein will be addressed collectively as they apply to all of the related actions noted above. Any distinction in the claims or the actions in which they were asserted will be specifically noted.

A. Plaintiffs' Complaints Fail To Sufficiently Allege Claims for Negligence

1. Maryland law does not impose any of the "duties" alleged by Plaintiffs in their Complaints

In Count I of their respective Complaints, Plaintiffs set forth what appears to be a laundry list of "duties" that the Box Hill Defendants allegedly owed to them as a result of the physician-patient relationship. Under the guise of these "duties," it is essentially alleged that the Box Hill Defendants were required to inspect, investigate, and otherwise supervise NECC's compounding procedures, testing and safety policies, and its production facilities. Plaintiffs couch these "duties" as engaging in a "due diligence" of sorts prior to lawfully purchasing preservative-free MPA (hereinafter "MPA") from NECC. However, no such duties exist under Maryland law, and certainly did not exist at the time giving rise to the alleged causes of action in the above cases. Accordingly, Count I of Plaintiffs' respective Complaints fails to state a claim upon which relief can be granted.

Under Maryland law, a plaintiff must allege sufficient facts to meet each element of a medical negligence claim, namely (1) the existence of a duty, (2) a breach of the duty, (3) that the plaintiff suffered actual injury or loss, and (4) that the loss or injury proximately resulted from the defendant's breach of the duty. *See Dehn v. Edgecombe,* 384 Md. 606, 619, 865 A.2d 603, 611 (2005); *Horridge v. Social Services,* 382 Md. 170, 182, 854 A.2d 1232, 1238 (2004); *Patton v. USA Rugby,* 381 Md. 627, 635-36, 851 A.2d 566, 570 (2004). Under Maryland law, a court must begin its analysis of a negligence action with the question of whether a legally

cognizable duty exits. *Patton,* 381 Md. at 636, 851 A.2d at 571 (2004); *Remsburg v. Montgomery,* 376 Md. 568, 582, 831 A.2d 18, 26 (2003). Of significance, "[t]here can be no negligence where there is no duty that is due." *Patton,* 381 Md. at 636, 851 A.2d at 570 (citing *W. Va. Central R. Co. v. State ex rel. Fuller,* 96 Md. 652, 666, 54 A. 669, 671-72 (1903)). The existence of a duty in a negligence action is a question of law to be decided by the court. *Dehn,* 384 Md. at 619-20, 865 A.2d at 611; *see also Patton,* 381 Md. at 636, 851 A.2d at 570. There is no set formula for the determination of whether a duty exists. *Coates v. Southern Md. Electric,* 354 Md. 499, 509, 731 A.2d 931, 936 (1999). Maryland courts have applied a "foreseeability of harm" test, "which is based upon the recognition that duty must be limited to avoid liability for *unreasonably remote consequences*." *Doe v. Pharmacia & Upjohn Co.*, 388 Md. 407, 879 A.2d 1088, 1092-93 (2005) (emphasis added) (quoting *Coates,* 354 Md. at 509, 731 A.2d at 936). Duty is only an expression of the sum total of those considerations of policy which lead the law to say that that defendant owes a particular duty to that plaintiff under those circumstances. *Doe*, 879 A.2d at 1093 (internal quotations omitted). Further, duty "should be constructed by courts from building blocks of policy and justice." *Id.*

A duty, otherwise known as a standard of care when referring to medical negligence, is defined as what a reasonably prudent physician or health care provider would be required to do under same or similar circumstances in the care and treatment of a patient. *Board of Physicians v. Bernstein*, 894 A.2d 621, 645, 167 Md. App. 714 (2006). As Plaintiffs are aware, the actions of the Box Hill Defendants were on par with thousands of other physicians, clinics, and hospitals across the country in the same circumstances. Hundreds of those health care providers have been singled out and are now part of this MDL along with the Box Hill Defendants. Simply put, Maryland law does not impose a duty on physicians or medical clinics to regulate the pharmacies from which they lawfully purchase medications, nor does Maryland law impose a duty on

physicians to visit and/or evaluate a licensed pharmacy's compounding facility prior to purchasing medications as Plaintiffs have shockingly alleged. There is no authority supporting such a "due diligence" duty. Plaintiffs not only fail to provide support for such an imposition, but they also fail to cite to any case law that held or found such a duty because no such case law or support exists. In this instance, it is clear that it was the duty of the Massachusetts Board of Pharmacy,[7] not Dr. Bhambhani, a single Maryland physician, to regulate and license NECC and to ensure that NECC complied with Massachusetts pharmacy laws, established by the Massachusetts Board of Pharmacy.

Dr. Bhambhani and the Box Hill Defendants were well within their legal right to purchase medication from a fully licensed pharmacy that had fully licensed pharmacists and from whom thousands of other similarly situated physicians and clinics purchased medications and products, without ensuring that particular pharmacy's compliance with Massachusetts law. To further elucidate this point, Box Hill Defendants also purchase syringes, sterile dressings, sedatives, and other drugs and products that could potentially lead to serious injury, infection, and/or death if not handled appropriately by a manufacturer. Health care providers in a similar position to the Box Hill Defendants are not required under those circumstances, either, to first launch an investigation against each separate manufacturer and to make annual, unannounced visits to dozens of manufacturing facilities across the country throughout the year before they can purchase those other potentially dangerous products.

Further, Maryland law does not impose a duty on physicians and/or clinics, nor does it require them, to purchase medications from an FDA-regulated drug manufacturer as Plaintiffs suggest. Again, Plaintiffs' Complaints do not offer anything other than bald assertions and legal conclusions couched as facts to support those claims. Accordingly, the Box Hill Defendants were

[7] The Massachusetts Board of Pharmacy is also known as the "Massachusetts Board of Registration in Pharmacy."

fully permitted to purchase MPA from a compounding pharmacy, such as NECC, and doing so did not breach any duty owed to Plaintiffs.

Moreover, contrary to Plaintiffs' claims, the Box Hill Defendants also did not have a duty, nor were they required to, follow the American Society of Health-System Pharmacy ("ASHP") Guidelines on Outsourcing Sterile Compounding Services. They are simply "guidelines" that do not establish any duty or standard of care under Maryland law. Further, ASHP is a professional organization for health-system pharmacies. It is not a governing body that has any authority over the actions of Maryland physicians or clinics, including the Box Hill Defendants. Accordingly, none of the so-called "guidelines" promulgated by the ASHP establish or constitute a due diligence obligation for a physician, nor do they rise to the level of a duty imposed on a physician or clinic purchasing compounded medications.

As referenced above, Maryland courts have recognized that the existence of a duty "must be limited to avoid liability for *unreasonably remote consequences*." *Doe*, *supra*. The only duty imposed on the Box Hill Defendants was that they exercise reasonable care in their underlying care and treatment of the patients involved in these actions. This duty is and was premised on what other reasonable and similarly situated individuals and clinics in the medical community did, and how they acted, at the time that the care occurred—not traveling around the country to every manufacturer for every product that might lend itself to a dangerous situation, in order to oversee, inspect and ensure compliance. Pharmaceutical medications are by their very nature often "unavoidably unsafe products" with a known but apparently reasonable risk. *See* Restatement (Second) of Torts §402A, comment k (1965). Would it make sense that a physician would have to inspect the facility that manufactures Tylenol because adverse reactions might develop? Combined with the fact that state and federal licensing agencies and regulators are also required to regulate, license, and oversee manufacturers, like the Massachusetts Board of

Pharmacy and the FDA to NECC, Plaintiffs' suggestion that the Box Hill Defendants also had that duty would be insincere at best and ludicrous at worst.

Unfortunately, Plaintiffs try to do just that and invent a completely new duty for which there is no support. Consistent with the practices of her reasonable peers, Dr. Bhambhani and other physicians (and the Box Hill Defendants) do not have a duty to regulate pharmacies or to engage in any type of special due diligence inspection or investigation prior to lawfully purchasing medications from a licensed pharmacy, such as NECC. Maryland law has never recognized any such duties with respect to physicians and/or clinics and the imposition of the same would mark a drastic expansion of existing law, and one better left to the legislature and policy makers, not the courts. The Complaints, therefore, fail to allege a viable duty. Consequently, Count I of Plaintiffs' Complaints fail to state a claim upon which relief can be granted and must be dismissed.

2. Plaintiffs' Complaints fail to allege that the Box Hill Defendants breached an actual recognizable standard of care

Apart from misrepresenting the recognizable duties imposed on the Box Hill Defendants as health care providers, Plaintiffs fail to allege that Dr. Bhambhani breached a recognizable duty or standard of care that actually does exist—namely, how other reasonably prudent health care providers would act under same or similar circumstances in treating their patients. Dr. Bhambhani, like thousands of other physicians with her credentials, administers epidural steroid injections to treat her patients' pain. Such treatment is wide-spread and accepted in the medical community for patients who suffer from back and neck pain. That is uncontroverted. Plaintiffs, however, fail to allege that Dr. Bhambhani, for example, used a negligent technique or otherwise breached accepted standards of care as it pertains to the actual treatment that she provided to the underlying patients in these actions. As such, Count I of the Complaints fails to state an actionable claim upon which relief can be granted.

3. Plaintiffs' Complaints fail to sufficiently allege causation

Causation is an essential element of a negligence claim. For a plaintiff to recover damages, a defendant's negligence must be a cause of a plaintiff's injuries. *Supra*. The causation element consists of factual and proximate cause. Factual cause is the "but for" aspect of causation. A negligent act is only deemed the factual cause of an outcome if, in the absence of the act, the outcome would have been avoided. *See Peterson v. Underwood*, 258 Md. 9, 16, 264 A.2d 851 (1970). If there is no causation in fact, then there needs to be no further analysis because the causation element is insufficient. *Mackin v. Harris*, 342 Md. 1, 8, 672 A.2d 1110 (1996). If there is causation in fact, the inquiry continues to proximate cause.

Proximate cause ultimately involves a conclusion that someone will be held legally responsible for the consequences of an act or omission. This determination is subject to considerations of fairness or social policy as well as mere causation. *See Yonce v. Smithkline Beecham Clinical Lab*, 111 Md.App. 124, 680 A.2d 569 (1996). Negligent acts (such as a breach of a standard of care) are not actionable unless the injury is the natural and probable result or consequence of the negligent act or omission. *Medina v. Meilhammer*, 62 Md.App. 239, 489 A.2d 35 *cert. denied*, 303 Md. 683, 496 A.2d 683 (1985). Often proximate cause is not proven because the negligent act was too far removed from the harm or the nature or extent of the harm was unforeseen. *See Peterson*, 258 Md. at 18-20. Further, the actor's conduct may be held not to be a legal cause of harm where after the event, looking back from the harm to the actor's negligent conduct, it appears to the court highly extraordinary that it should have brought about the harm. *Hartford Ins. Co. v. Manor Inn*, 335 Md. 135, 157 n. 6, 642 A.2d 219. (1994). Moreover, an intervening cause, whether superseding or responsible, can break the chain of proximate causation if the negligence would have occurred even without the initial actor's alleged negligence. *See Yonce, supra.* As suggested, this is a determination made by the Court if

the facts of the underlying action are not disputed, *Lashley v. Dawson*, 162 Md. 549, 563, 160 A. 738 (1932), as is the case here.

Plaintiffs' claims fail as to causation. Plaintiff patients were harmed by contamination of the MPA, which resulted from NECC's failure to properly manufacture and utilize appropriate sterility practices while compounding MPA. The actions taken by the Box Hill Defendants simply had nothing to do with the actual cause, or cause-in-fact, of the contamination, and the alleged acts of negligence by the Box Hill Defendants are too remotely connected. Further, the intervening (and fraudulent) acts of NECC are too unforeseeable to satisfy a causal connection between the alleged negligence of the Box Hill Defendants and the injuries allegedly sustained by these patients.

For example, it is alleged that the Box Hill Defendants were negligent in failing to provide patient-specific prescriptions and/or in providing "fake" patient lists in order to purchase medication from NECC. Assuming arguendo that such allegations are true, which they are not, such allegations are also insufficient to plead causation, either factual or proximate. NECC's failure to properly manufacture and apply proper sterility and testing practices as to MPA was the source of the contamination, not an alleged failure to provide patient-specific prescriptions. In other words, even assuming that the Box Hill Defendants had provided patient-specific prescriptions to the satisfaction of the Plaintiffs in this case, that would not have caused otherwise contaminated medication to transform into an unadulterated form to be administered to the Plaintiff patients. Plaintiffs do not plead otherwise. The Box Hill Defendants still would have received contaminated medication from the same supply, the patients still would have been injected with that medication, and the same outcome would have resulted. Therefore, the contamination would have occurred independent of the ordering practices of the Box Hill Defendants, so the "but for" test fails and a negligent superseding cause can also be shown. The

same conclusions can be drawn by the Court as a follow-up to any of the other allegedly negligent acts committed by the Box Hill Defendants. Consequently, Count I of Plaintiffs' Complaints must also be dismissed because the causation element of a negligence claim is lacking and relief cannot possibly be granted.

B. Plaintiffs' Complaints Fail To Sufficiently Allege Lack of Informed Consent

In Count II of their respective Complaints, Plaintiffs allege that the Box Hill Defendants did not afford Plaintiff patients informed consent. Plaintiffs allege that the Box Hill Defendants provided high risk, unreasonably dangerous, and contaminated drugs to the Plaintiff patients. Plaintiffs then allege that the Defendants failed to inform them that they would be administered this type of drug instead of a "high quality" drug produced by an FDA regulated manufacturer. Plaintiffs acknowledge that the patients were presented with, and read, reviewed, and relied upon a consent form, but then baldly assert that the consent form did not inform them about the "risks" and benefits of the procedure to which they had consented. Shockingly, Plaintiffs allege that this was an act by the Box Hill Defendants because they were concerned that the patients would refuse treatment and the Defendants would lose profits. Plaintiffs, however, do not allege that the patients, or more correctly, a reasonable person in the patients' positions, would have withheld consent to therapy.

Under Maryland law, before a physician provides medical treatment to a patient, the physician is required to explain the treatment and warn of "material" risks or dangers, so that the patient can make an intelligent and informed decision about whether to go forward with the proposed treatment. *See Sard v. Hardy*, 281 Md. 432, 379 A.2d 1014 (1977). A physician is not required to disclose all risks. The scope of a physician's duty to inform is limited to "material" information, which means, for example, a risk that a physician knows or should know would be significant to a reasonable person in the patient's position. *Sard v. Hardy*, 281 Md. 432, 379

A.2d 1014 (1977). Causation is also an element of informed consent, and the appropriate test is whether a reasonable person would withhold consent to therapy. *Id.*

First, Plaintiffs' factual claim concerning the consent form is troubling. Plaintiffs acknowledge that each patient was provided a consent form and that each patient read and relied upon that form when consenting to treatment. *See* Consent Forms for each Plaintiff patient, attached cumulatively as Exhibit 1. Likely realizing that their informed consent claims were in jeopardy, Plaintiffs then allege in their Complaints, however, as noted above, that the Defendants did not inform them about the risks or benefits of the procedure to which they had consented. This is an utter misstatement of the facts, which bears mention, as it certainly cannot be supported by any real proof, as can be seen from the consent forms. The consent form explains exactly what procedure was to be performed and where; it also references 17 material risks of the procedure based on Dr. Bhambhani's experience, and the nature and purpose of the procedure (benefits) and alternatives to the procedure. The consent form also notes: "I have read and fully understand the above consent…" Each consent is signed at the bottom by the patient and Dr. Bhambhani. Accordingly, while Plaintiffs simply use unsupported conclusory language in the Complaints, these consent forms make clear that Plaintiffs allegations are misleading, if not false. Even if it cannot be used for any other determinative purpose in this Memorandum or for the Motions to Dismiss, the consent forms should make the Court wary of the possible liberties taken in Plaintiffs' other claims.

Putting aside the factual inaccuracies in Plaintiffs' Complaints for a moment, and the fact that several of the patients had previously undergone the same procedure with the Box Hill Defendants, involving the same risks, benefits and consent, Plaintiffs misrepresent the informed consent doctrine. On the face of the Complaints, Plaintiffs simply allege that the Box Hill Defendants failed to identify certain "risks." At no point do they allege that Defendants failed to

disclose a "material" risk. Maryland law does not require a physician to name every possible risk, only the material ones. Further, Plaintiffs conclude that the drugs provided to the Plaintiffs were "riskier" and more dangerous than those that could have been purchased from some other yet unidentified pharmacy. Riskier or more dangerous than what? Would that alleged increase in risk make it material to a reasonable person? Plaintiffs mention drugs manufactured by the FDA, but simply suggest that they are less risky and less dangerous without more helpful guidance. The claims in the Complaints are insufficient to make such a determination. Plaintiffs did not meet their burden.

Most importantly, it is essentially alleged that the Box Hill Defendants were required to inform the patients that they were going to be injected with contaminated drugs. However, Maryland law is clear that a physician has no duty to disclose a risk of which he does not know and should not have been aware. Plaintiffs allege no facts to support that the Box Hill Defendants knew that the drugs were actually contaminated. The consent forms in Exhibit 1 make clear that Dr. Bhambhani warned of the risks of infection, organ damage, nerve damage, and headache, among more than 13 others, but there is no allegation other than a bald assertion that she knew the vials of MPA were contaminated or any riskier than any other time she had injected a patient with any drug. To hold the Box Hill Defendants to a higher standard runs contrary to Maryland law. Accordingly, Count II of Plaintiffs' respective Complaints fails to state a claim upon which relief can be granted and must be dismissed.

C. Plaintiffs Consented To The Steroid Injections at Issue, So There Is Not a Viable Claim for Battery.

Under Maryland law, "[a] battery occurs when one intends a harmful or offensive contact with another without that person's consent." *Nelson v. Carroll*, 355 Md. 593, 600 (1999) (citing RESTATEMENT (SECOND) OF TORTS § 13 (1965)). *See also Saba v. Darling*, 320 Md. 45, 49 (1990) (stating that "[a] battery has been defined as a harmful or offensive contact with a

person resulting from an act intended to cause the person such contact"). In a medical setting, a battery is reserved for those circumstances when a doctor performs an operation to which the patient has not actually consented to or authorized the treatment. *Mole v. Jutton,* 381 Md. 27, 39, 47, 846 A.2d 1035, 1046-47 (2004). If the patient consents to certain treatment, which the doctor performs, and a patient suffers a complication without intentional deviation from the consent given, the action should be pleaded in negligence. *Id.* at 39, 47, 846 A.2d at 1042, 1046-47; *Faya v. Almaraz,* 329 Md. at 435, 620 A.2d at 327 (information provided to (or withheld from) a patient is the crux of an informed consent action sounding in negligence as opposed to battery).

In the instant Complaints, Plaintiffs allege a battery in Count III against the Box Hill Defendants. The procedure at issue is the performance of epidural steroid injections. As Maryland law makes clear, if the Plaintiff patients consented to the performance of the steroid injections, then they are unable to establish the elements of a battery claim. In a weak attempt to establish their claim for battery, Plaintiffs allege that they "did not consent to the injection of contaminated drugs into [their] bodies." However, in Count II, which was adopted by reference in Count III, Plaintiffs allege that:

> "[m]any, if not all, of the Clinic Related Defendants prepared a Consent for Treatment form…which [Plaintiff patients] read and relied upon when agreeing to accept treatment, [but it] failed to inform [Plaintiff patients] of the risks and benefits of the procedure before it was performed." (*Handy*, ¶ 205.)[8]

Thus, even when accepting all of Plaintiffs' allegations as true, they admit to receiving, reading and relying on a consent form prior to agreeing to undergo steroid injections. In other words, regardless of what label they put on the claim, the Plaintiff patients authorized or consented to the performance of an epidural steroid injection, which does not support a claim for battery.

[8] While they are not necessarily found in the same numbered paragraph, an identical allegation was made in each of the Complaints under Count II.

In an August 29, 2014 "Memorandum of Decision," this Court examined identical claims of battery against other health care provider defendants in this MDL and dismissed the battery claims in those actions on similar, if not identical grounds. (1:13-md-2419, Doc. 1360.) Consequently, and based on the above reasons as applied to Maryland law, Count III also fails to state a claim upon which relief can be granted and must be dismissed.

D. Plaintiffs' Claims of Agency Must Be Dismissed as a Matter of Law For Failing To State a Claim Upon Which Relief Can Be Granted

All of the Plaintiffs in the above actions allege claims for respondeat superior against the Box Hill Defendants as to NECC in Count IV, except in *Handy*, which makes no such claim. As such, this section does not apply to *Handy*. The relevant Plaintiffs seek to hold the Box Hill Defendants vicariously liable for the conduct of NECC, alleging that NECC was acting as the Box Hill Defendants' agent. Plaintiffs claim that a consensual fiduciary relationship arose when the Box Hill Defendants contracted with NECC to procure medication for their patients and that NECC consented to act as the Box Hill Defendants' agent, and in their interest, when compounding and delivering their drugs to Box Hill. (*See* Complaints, Count IV); *see also* Memorandum of Decision in a related MDL action involving the same claims (1:13-md-2419, Doc. 1360). Plaintiffs also allege that the Box Hill Defendants controlled the procurement of the NECC drugs and that NECC acted within the scope of its agency when it negligently compounded drugs on behalf of the Box Hill Defendants. *Id.*

Generally, under Maryland law, a principal is vicariously liable for the negligence of its agent when the two share a master-servant relationship, but not when the agent is merely an independent contractor of the principal. *Sanders v. Rowan*, 61 Md.App. 40, 51, 484 A.2d 1023 (1984). There are three elements that are integral to an agency relationship: (1) The agent is subject to the principal's right of control; (2) the agent has a duty to act primarily for the benefit

of the principal; and (3) the agent holds a power to alter the legal relations of the principal. *Schear v. Motel Management Corp. of America*, 61 Md.App. 670, 688, 487 A.2d 1240, 1248 (1984). Ultimately, however, it is the control element that is instrumental in proving the existence of an agency or master/servant relationship because a master "controls or has the right to control the physical conduct of the [servant] in the performance of the service." *Id.* at 687; *see also B.P. Oil Corp. v. Mabe*, 279 Md. 632, 370 A.2d 554 (1977). Further, "[i]t is the element of continuous subjection to the will of the principal which distinguishes the agency agreement from other agreements." Restatement (Second) of Agency § 1(1) comment b (1957) (emphasis added).

Plaintiffs' allegations, however, are clearly insufficient to support an agency relationship between the Box Hill Defendants and NECC based on Maryland law. At best, NECC was a vendor from whom the Box Hill Defendants ordered medications to be administered to patients, just like the Box Hill Defendants order other products and medications from other companies. Moreover, NECC had this vendor relationship with hundreds of entities around the country, including the other health care provider defendants in the other cases in the MDL. Now, Plaintiffs wish to allege that NECC was the agent of all of these clinics in the MDL and that the clinics acted as principals and are responsible for NECC's actions and inactions. NECC's duty as a business was not to act primarily for the benefit of the Box Hill Defendants, but to sell products to all-comers for the purpose of creating revenue. Plaintiffs' assertion that NECC acted within the scope of its agency when it negligently compounded drugs on behalf of the Box Hill Defendants would be laughable if these allegations were not so serious.

Maryland law explains that the control element is the most important aspect in determining agency. If a principal is to be responsible for the actions or inactions of his or her subordinate, the principal must have ultimate responsibility to control the end result of his or her agent's actions. *Id.*; *see also*, *supra*. The Box Hill Defendants did not maintain any kind of

control over NECC. By way of examples, the Box Hill Defendants did not control: (1) the manner and means by which NECC performed their duties; (2) how and where NECC manufactured MPA; (3) what stock solutions NECC used; (4) what sterility policies they enacted and/or followed; (5) how they cleaned their so-called "clean rooms;" (6) how the clean rooms were designed and maintained; (7) what HVAC system was used in the clean rooms or whether it was sufficient from an engineering perspective for NECC's needs; (8) what pharmacists and technicians NECC chose to employ or terminate; (9) employee schedules, salary, or benefits; (10) how much NECC charged others for their products; (11) where the raw ingredients for MPA were purchased or how they were stored; (12) how long NECC used the autoclave to sterilize non-sterile ingredients or equipment; or even (13) what equipment NECC used in the clean rooms, among many other examples. Further, the Box Hill Defendants certainly had no control over NECC's decision to mislabel drugs with fake "expiration" dates or testing compliance, which was discovered after the fact by the CDC and FBI. The above examples make clear the absence of any control by the Box Hill Defendants over NECC, thereby disproving any alleged agency relationship. While the Box Hill Defendants paid NECC for the compounded MPA, they could have stopped ordering it at any time, as they did the moment the recall notice was received.

Aside from the complete lack of control actually and substantively, Plaintiffs certainly did not even plead sufficient facts in Count IV of the indicated Complaints to adequately allege the control needed to establish an agency relationship for which the Box Hill Defendants would be vicariously liable. Accordingly, as this Court also did for other defendants through Doc. 1360, Count IV in all of the instant actions except for *Handy* (No: 1:14-cv-14019-RWZ), should be dismissed for failure to state a claim upon which relief can be granted.

E. Plaintiffs' Claims of Civil Conspiracy Must Be Dismissed

Plaintiffs all allege a claim for civil conspiracy between the Box Hill Defendants and NECC. The claims are found under Count XI in the *Handy* case and under Count V in all of the other related cases. Plaintiffs' claims, however, all fail to allege with any particularity an intention to agree or conspire to intentionally commit a wrongful act. Furthermore, Plaintiffs have failed to allege that the purported civil conspiracy caused the MPA to be contaminated. In *Handy* (No: 1:14-cv-14019-RWZ), Plaintiffs allege that a conspiracy was created to defraud the Massachusetts Board of Pharmacy and circumvent their requirements. The alleged fraud was not alleged to have been directed to the Plaintiffs. In the other actions addressed here, Plaintiffs' identical claims utilize a single numbered paragraph, which provides no factual allegations or particularity to explain or support such a claim other than just baldly asserting that civil conspiracy exists.

The law in Maryland is essentially identical to the underlying law explained by other jurisdictions and summarized by this Court in Doc. 1360 of this MDL. In Maryland, to recover damages for civil conspiracy, it must be shown that there was an agreement by "two or more persons to accomplish an unlawful act or to use unlawful means to accomplish an act that is not in and of itself illegal, with the further requirement that the act or the means employed must result in damages to the plaintiff." *Hoffman v. Stamper*, 385 Md. 1, 24, 867 A.2d 276, 290 (2005) (quoting *Green v. Wash. Suburban Sanitary Comm'n*, 259 Md. 206, 221, 269 A.2d 815, 824 (1970)); *see also Mackey v. Compass*, 892 A.2d 479, 391 Md. 117 (2006). A plaintiff must prove an unlawful agreement, the commission of an overt act in furtherance of the agreement, and that as a result, the plaintiff suffered actual injury. *Hoffman*, 385 Md. at 25, 867 A.2d at 290. Most importantly, the unlawful agreement is not actionable by itself; rather, the "[t]ort actually lies in the act causing the harm" to the plaintiff. *Id.* Thus, civil conspiracy is not "capable of

independently sustaining an award of damages in the absence of other tortious injury to the plaintiff." *Id.* (internal citations and quotations omitted).

Plaintiffs' allegations in the instant actions are also equally similar, if not identical, to the ones underlying the Court's ruling as memorialized in Doc. 1360. The Plaintiffs were allegedly injured by contaminated steroids manufactured by NECC. In short, however, Plaintiffs have failed to plead with any specificity or even generally how the actions of the Box Hill Defendants, providing prescriptions or patient names, caused the steroids to become contaminated while manufactured by NECC. Further, Plaintiffs have failed to plead that Box Hill Defendants intentionally conspired with NECC to contaminate the steroids. The Complaints allege, directly or through adoption, that the conspiracy involved NECC's request that the Box Hill Defendants provide patient names for patients to whom they intended to administer MPA. Plaintiffs allege that NECC used the patient names provided by the Box Hill Defendants to defraud the Massachusetts Board of Pharmacy and circumvent its patient safety requirements. Plaintiffs, however, fail to allege how such a practice, even if true, caused any injury to Plaintiffs, or even that it did. Like in *Hoffman*, 385 Md. at 25, 867 A.2d at 290, the alleged conspiracy to trick the Massachusetts Board of Pharmacy did not cause meningitis and/or death and cannot otherwise stand on its own as an actionable tort upon which Plaintiffs can base a claim of civil conspiracy. As such, Plaintiffs are not entitled to relief, and their civil conspiracy claims in Count XI in Handy and in Count V of all of the other Complaints should be dismissed, as the Court has previously done in other cases through Doc. 1360.

F. Plaintiffs' Claims of Strict Liability Against the Box Hill Defendants For Administering Medication To A Patient Are Misplaced and Must Be Dismissed.

Plaintiffs in all of the related actions except for *Handy* (No: 1:14-cv-14019-RWZ) have alleged a claim for strict liability against the Box Hill Defendants in Count VI of the Complaints.

The relevant Plaintiffs' claims, however, are misplaced, and the Box Hill Defendants, in their capacity as health care providers who provided a skilled medical service, are not subject to strict liability. Moreover, Plaintiffs fail to sufficiently allege any facts that would permit them to recover strict liability damages from the Box Hill Defendants.

Strict liability results when a manufacturer or seller of any product in a defective condition that is unreasonably dangerous subjects a user to physical harm resulting from the defect, provided: (1) the defect was in a defective condition at the time it left the possession or control of the seller, (2) the product was unreasonably dangerous, (3) the defect was the cause of the injury, and (4) the product was expected to and did reach the user without substantial change in condition. *See Phipps v. General Motors Corp.*, 278 Md. 337, 363 A.2d 955

Plaintiffs allege that the Box Hill Defendants, who administered the NECC-manufactured steroid injections to the patients in this case, are liable for being in the chain of distribution of a defective product as a seller, which is not true. The Defendants are not sellers of MPA, nor do they charge their patients separately from the procedure for the MPA in an epidural steroid injection. The MPA is an indispensable part of a consented-to procedure to treat patients' serious back and neck pain.

Even assuming Plaintiffs' allegations to be true that Defendants are "sellers" for purposes of this argument, however, Plaintiffs ignore well-established Maryland case law precluding this very claim against the Box Hill Defendants. For background, Md. Code Ann., Com. Law Art., § 2-105, defines "goods" as "all things (including specifically manufactured goods) which are movable at the time of identification to the contract for sale…," which would include the MPA supplied to Dr. Bhambhani by NECC in this case. *See also Rite Aid Corp. v. Levy-Gray*, 391 Md. 608, 894 A.2d 563 (2006). Plaintiffs allege that by injecting these defective products into

Plaintiff patients and/or charging for them, the Box Hill Defendants were selling goods or otherwise distributing the "goods" to each individual patient.[9]

Nevertheless, Maryland law on strict liability claims against health care professionals is clear. Strict liability does not apply when a service provided to a patient involves the application of medical skill, whereby the service predominates the product. *Roberts v. Suburban Hospital Assoc.*, 73 Md.App. 1, 532 A.2d 1081 (1987) (emphasis added). The Court of Appeals made clear that the sale (of goods) is the predominant factor in any hybrid contract only when "the thrust [and] the purpose, reasonably stated, is a transaction of sale with labor incidentally involved." *Burton v. Artery Company*, 279 Md. 94, 367 A.2d 935 (1977).

This predominance concept is supported by the *Roberts* case. In *Roberts*, the plaintiff received a blood transfusion and contracted HIV. The plaintiff claimed that a blood transfusion was a sale of goods, and he filed suit against a hospital claiming strict liability. *Id.* In *Roberts*, the Court of Special Appeals dismissed the claim of strict liability on the basis that the blood transfusion constituted the provision of a service rather than a sale of goods. Specifically, the Court of Special Appeals noted that a transfusion is not just a sale of blood that the patient takes home in a package. *Id.* The transfusion of the blood – the injecting of it into the patient's bloodstream – is what the patient really needs and for which he pays. The service involves the application of specialized medical skill. *Id.* In other words, the patient is not buying a blood product to take it home and transfuse him or herself. The patient requires the expertise and skill of the health care provider to provide a service. *Id.*

Of course, the facts in the *Roberts* case are similar to the facts involving the instant cases and the Box Hill Defendants. The patients here were not buying MPA to take home or to use as

[9] As stated previously, the Box Hill Defendants simply charge for the procedure and not separately for the drugs. The Box Hill Defendants are not selling or distributing the drug to their patients, and they do not concede to being in the chain of distribution. That said, the Defendants assume Plaintiffs underlying allegations to be true for purposes of this argument.

they saw fit. They were paying for the procedure for which the MPA was an integral part. As the steroid injections are given epidurally,[10] each patient depended on Dr. Bhambhani's special skill and expertise to inject just the right amount of MPA into the exact location in each patient's back (or back of the neck), with a long needle approaching a certain distance from the spine using fluoroscopic (x-ray) guidance for maximum effectiveness and pain relief. Further supporting the skill required for this procedure are the many risks of performing the procedure incorrectly or haphazardly, just like if a blood transfusion is given using an incorrect blood type. An epidural injection can sometimes even cause temporary or permanent paralysis even absent negligence. This procedure is not something that any of the Plaintiffs could have done without specialized expertise and training, which Dr. Bhambhani possessed.

Like in *Roberts*, what occurred in the instant actions should not be considered a sale of goods as anticipated by the Commercial Law Article or the Restatement (Second) of Torts. For example, the Restatement describes the "business of selling" as any person engaged in the business of selling products for use or consumption. *Id.* However, Dr. Bhambhani is a physician who was treating patients for their chronic pain. She is not "in the business of selling products" and the patients needed Dr. Bhambhani to perform the procedure using the drugs. Accordingly, without Dr. Bhambhani's medical skill and expertise, the drugs in this case would be useless on their own and her care goes far beyond just a sale or distribution of goods on which these Plaintiffs would like this Court to focus. The service clearly predominates over the product as evidenced above and by the ruling in *Roberts, et al.* As such, Plaintiffs are unable to maintain a

[10] The injections are given in the back, so patients cannot do it themselves, even if they had the proper skill and experience.

claim against the Box Hill Defendants for strict liability, and Count VI in all of the actions except for *Handy*, in which the claim was not made, should be dismissed.[11]

To be thorough, Plaintiffs also cite to Md. Code Ann., Cts & Jud. Proc. Art. ("CJP"), § 5-405(c)(1), for the premise that the Box Hill Defendants can be sued if the actual manufacturer (NECC in this case) is insolvent or judgment proof. However, CJP 5-405(c)(1) does not provide a separate cause of action for Plaintiffs under those circumstances. Rather, 5-405(c)(1) simply eliminates the "sealed container defense" (as it is known) as a possible defense for a defendant who can otherwise be validly sued under some independent cause of action. While the Box Hill Defendants do not concede this issue, it is not necessary to address for purposes of defending the claims against them because the premise ignores the aforementioned Maryland law which precludes any strict liability cause of action against these Defendants anyway.

Accordingly, Plaintiffs' claims of strict liability against the Box Hill Defendants are misplaced and Count VI in all of the actions except for *Handy*, in which the claim was not made, must be dismissed because they fail to state a claim upon which relief can be granted.

G. Plaintiffs' Claims of Consumer Protection Violations Under Maryland and Massachusetts Law Do Not Apply To Medical Providers Such as the Box Hill Defendants and Must Be Dismissed

Plaintiffs attempt to assert a claim against the Box Hill Defendants for purported violations of consumer protection statutes in Maryland and Massachusetts, including the Maryland Consumer Protection Act, codified by Md. Code Ann., Com. Law Art. ("CL"), §§ 13-101, et seq., as well as the Mass. Gen. Laws Ann. Ch. 93A, et seq., respectively. This claim is made in Count XII of *Handy* (No: 1:14-cv-14019-RWZ) and in Count XI for all of the other related instant actions. The Box Hill Defendants, however, are not subject to either of these

[11] As in several previous claims, this Court also dismissed strict liability claims against other health care providers in this MDL for various reasons, as can be found, for example, in Doc. 1360.

statutes and all claims against the Box Hill Defendants alleging these violations must be dismissed.

The Maryland Consumer Protection Act (hereinafter "MCPA") protects consumers from "unfair or deceptive trade practices," as alleged by Plaintiffs. CL 13-105 However, the statute expressly states that the MCPA "does not apply to…the professional services of…medical or dental practitioners. CL 13-104. Maryland courts have also dismissed claims against Maryland physicians and practice groups under the MCPA, not just for alleged unfair and deceptive trade practices and services provided, but also for services indirectly related to the provision of professional services. *See Scull v. Doctors Groover, Christie & Merritt, P.C.*, 45 A.3d 925, 205 Md.App. 567 (2012). It is undisputed that the Box Hill Defendants are medical practitioners and providers. Consequently, Plaintiffs are unable to maintain claims against the Box Hill Defendants for violations of the Maryland Consumer Protection Act, and their claims must be dismissed.

Likewise, Plaintiffs claim that the Box Hill Defendants violated consumer protection laws found in Mass. Gen. Laws Ann., Ch. 93A, et seq., which is also intended to protect consumers from unfair or deceptive trade practices" *See* Ch. 93A(2). However, that statute specifically states that it only applies to the "sale…of any services and…any trade or commerce directly or indirectly affecting the people of [Massachusetts]." Ch. 93A(1)(b). It is undisputed that none of the Plaintiff patients (nor are the Box Hill Defendants) residents of or subject to the laws of the Commonwealth of Massachusetts. As such, Plaintiffs' claims that the Box Hill Defendants violated Mass. Gen Laws Ch. 93A cannot be maintained and must be dismissed.

Since all of Plaintiffs' claims related to alleged violations of consumer protection laws in Maryland and Massachusetts fail to state a claim upon which relief can be granted, Count XII in *Handy* and Count XI in the rest of the related instant cases must be dismissed.

H. Plaintiffs' Claims of Wrongful Death Must Be Dismissed

Plaintiffs allege a claim for wrongful death against the Box Hill Defendants for the death of a Plaintiff decedent in the following cases and corresponding counts:[12]

Handy (No: 1:14-cv-14019-RWZ) – Count XIII
Armetta (No. 1:14-cv-14022-RWZ) – Count XIII – XV
Kashi (No. 1:14-cv-14026-RWZ) – Counts XIII - XVII
Bowman (No. 1:14-cv-14028-RWZ) – Count XIII

Plaintiffs cite to Md. Code Ann., Cts. & Jud. Proc. Art. ("CJP"), § 3-904 and Maryland Rule 15-1001. Plaintiffs failed to cite Cts. & Jud. Proc. Art. §§ 3-901, 3-902, and 3-903, which also apply. Wrongful death is defined as "an action…against a person whose wrongful act causes the death of another. CJP 3-902. Further, a "wrongful act" is defined as "an act, neglect, or default including a felonious act which would have entitled the party injured to maintain an action and recover damages if death had not ensued. CJP 3-901.

While it is a separate cause of action, a wrongful death claim is based on some underlying "wrongful act." While Plaintiffs baldly allege that the Box Hill Defendants caused the death of each Plaintiff decedent by their "fraud, intentional, and negligent conduct," (*see* Identified Complaints and Counts, *supra*), they have failed to plead sufficient facts to support the underlying wrongful acts as examined previously in the instant Motions to Dismiss and this Memorandum. For example, Plaintiffs have not properly pleaded a claim for negligence, lack of informed consent, battery, respondeat superior, civil conspiracy, strict liability, or violations of consumer protection statutes, which cumulatively address alleged negligence, intentional torts, and fraud. Plaintiffs have also failed to plead facts to support their bald allegations of the elements of these claims. In short, Plaintiffs have not shown that Dr. Bhambhani's performance of the medical procedure was actually negligent, such as her technique in injecting the drugs, or

[12] This section does not apply to *Torbeck* (No. 1:14-cv-14023-RWZ), *Dreisch* (No. 1:14-cv-14029-RWZ), *Davis* (No. 1:14-cv-14033-RWZ), or *Farthing* (No. 1:14-cv-14036-RWZ). Reference to "Plaintiffs" only refer to the wrongful death Plaintiffs in the cases and Counts identified.

that she intentionally injected steroids that she knew were contaminated. As such, should the claims underlying a wrongful death action be dismissed as requested above, so to should Plaintiffs' wrongful death claims, as they require an underlying wrongful act as it relates to the Box Hill Defendants.

In addition, to the extent that any of the above claims failed to include a necessary wrongful death plaintiff/beneficiary, which is unknown to the Box Hill Defendants at this time, the Box Hill Defendants also reserve and/or seek dismissal of an above-listed individual wrongful death claim on those grounds, pursuant to Maryland Rule 15-1001(b) ("All persons who are or may be entitled by law to claim damages by reason of the wrongful death shall be named as plaintiffs whether or not they join in the action").

I. Plaintiffs' Claims for Loss of Consortium Must Be Dismissed

Plaintiffs allege a claim for loss of consortium against the Box Hill Defendants in the following cases and corresponding counts:[13]

Handy (No: 1:14-cv-14019-RWZ) – Count XIII
Davis (No. 1:14-cv-14033-RWZ) – Count XIII
Farthing (No. 1:14-cv-14036-RWZ) – Count XIII
Dreisch (No. 1:14-cv-14029-RWZ) – Count XIII
Torbeck (No. 1:14-cv-14023-RWZ) – Count XIII

A claim for loss of consortium arises from the loss of society, affection, assistance, and conjugal fellowship suffered by the marital unit as a result of the physical injury to one spouse through the tortious conduct of a third party. *Deems v. Western Maryland Railway Company*, 247 Md. 95, 100, 231 A.2d 514 (1967). Although a loss of consortium claim is an independent action eligible for an independent recovery, *Deems,* 247 Md. at 115-16, it is derivative of an injured spouse's claim for personal injury. *Oaks v. Connors,* 339 Md. 24, 38, 660 A.2d 423 (1995) (emphasis added). As such, a loss of consortium claim cannot stand on its own. To the

[13] This section does not apply to *Armetta* (No. 1:14-cv-14022-RWZ), *Kashi* (No. 1:14-cv-14026-RWZ), or *Bowman* (No. 1:14-cv-14028-RWZ). Reference to "Plaintiffs" only refer to the Plaintiffs in the cases identified.

extent that the other claims in Plaintiffs' Complaints alleging liability against the Box Hill Defendants are dismissed as requested, these loss of consortium claims must also be dismissed for failure to state a claim upon which relief can be granted.

Further, in the *Handy* case, all Plaintiffs claim loss of consortium in Count XIII in accordance with their wrongful death claims. However, loss of consortium damages only accrue to a spouse of the injured party. *Oaks v. Connors,* 339 Md. at 34 (emphasis added). Accordingly, the loss of consortium claims made in *Handy* should be dismissed as to all of the non-spouse Plaintiffs for this reason as well.

J. Plaintiffs' Allegations are Insufficient to Support a Punitive Damages Claim Under Maryland Law

Plaintiffs in all of the above related actions have attempted to assert a punitive damages claim. However, none of the allegations are sufficient to support a punitive damages claim. As explained previously, while Plaintiffs may attach numerous other labels to their claims, the actions underlying the instant cases involved the medical care of a patient by a health care provider. At least as to the Box Hill Defendants, the Maryland Health Care Malpractice Claims Act applies and the claims in the instant cases fall under alleged medical negligence. *Supra; see also* Md. Code Ann., Cts. & Jud. Proc. Art., §§ 3-2A-01, et seq. As it applies to these cases, Maryland law is clear that plaintiffs are required to show actual malice as a prerequisite to the recovery of punitive damages in medical malpractice actions. *Miller v. Schaefer*, 80 Md.App. 60, 68, 559 A.2d 813 (1988); *see also H & R Block, Inc. v. Testerman*, 275 Md. 36, 338 A.2d 48 (1975). Maryland courts have characterized actual malice as "the performance of an act…with an evil or rancorous motive influenced by hate…to deliberately and willfully injure the plaintiff." *Miller*, 80 Md.App. 60, 69, 559 A.2d 813 (quoting *Testerman*, 275 Md. at 43, 338 A.2d 48).

While Plaintiffs in the instant actions have thrown around the terms negligent, reckless, intentional, and fraudulent in trying to describe the Box Hill Defendants' actions, these

superfluous allegations without more do not satisfy the prerequisites of establishing a basis for punitive damages. Further, Plaintiffs have not and cannot point to any evidence that establishes that Dr. Bhambhani actually acted "with an evil or rancorous motive influenced by hate… to deliberately and willfully injure" the Plaintiff patients. *See Miller* and *Testerman*, *supra.* Not only do Plaintiffs not allege anything directly, but such a claim defies logic. To believe that punitive damages allegations against Dr. Bhambhani could survive and permit a recovery, one would have to believe that Dr. Bhambhani, a well-respected anesthesiologist for more than 20 years, as well as the hundreds of other health care provider defendants in this MDL who provided MPA to their patients (for whom these claims are also made), all decided on one or more days over the summer of 2012 to harm (or potentially harm) all of the patients that they treated. In addition, they also would have had to make that decision despite being unaware that the MPA they were administering was contaminated. The Court would also have to find that the Box Hill Defendants and all of the other health care provider defendants just happened to want to harm patients on the occasions when they were unknowingly administering contaminated steroids. Such a finding, especially given the current allegations would be an extraordinary leap to say the least, let alone unbelievable. Accordingly, Plaintiffs' claims for punitive damages are completely illogical and unsupported and must be dismissed.

V. CONCLUSION

The claims analyzed above must be dismissed as a matter of law according to the Federal Rules of Civil Procedure and the other applicable law as outlined above.

Respectfully submitted,

/s/ Gregory K. Kirby
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Attorneys for Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C.

CERTIFICATE OF SERVICE

I, Gregory K. Kirby, hereby certify that a copy of the foregoing document, filed through the CM/ECF system will be accessible to those attorneys who are registered with the Court's electronic filing system and Notice of Electronic filing (NEF), including the attorneys representing the plaintiffs in the above-referenced individual cases, and will be sent to these parties by operation of the CM/ECF system on January13, 2015.

/s/ Gregory K. Kirby
Gregory K. Kirby

Rozek, Brenda 8/31/2012 - 4003 Ritu T. Bhambhani MD

Box Hill Surgery Center
100 Walter Ward Blvd Unit 300, Abingdon, MD 21009

INFORMED CONSENT FOR PROCEDURE

ALLERGIES: No known medication allergies.

I hereby authorize Dr. Bhambhani to perform upon me,

Cervical/Thoracic/Lumbar/Caudal **Epidural Steroid Injection**
Selective Nerve Root Block B/L ~~R L L1 L2 L3~~ L4 L5 S1
Facet Medial Branch Nerve Blocks B/L R L L2-3 L3-4 L4-5 L5- S1
B/L R L C3-4, 4-5, 5-6, 6-7, 7-T1
Radio-frequency ablation Medial Branch Nerves B/L R L L2-3 L3-4 L4-5 L5-SI
Sacro-Iliac joint injection B/L R L

The diagnosis requiring this procedure is Back/Neck/~~Leg~~/Arm pain.
The nature of this procedure is to place a needle between or along the bones of my back or neck and inject medicine to reduce the swelling, inflammation and irritation around the nerves in an attempt to reduce/relieve my pain.

Material Risks of the Procedure:
As a result of the procedure being performed, there is the risk of:
INCREASED PAIN, LOSS OF BLOOD, SCARRING, INFECTION, ORGAN DAMAGE, ALLERGIC REACTION TO MEDICATIONS USED, SIDE EFFECTS FROM MEDICATIONS USED (fluid retention, congestive heart failure, rash, malaise, cramps), NERVE DAMAGE, NUMBNESS, TINGLING, HEADACHE, FAILURE TO WORK AS PLANNED.
*The nature and purpose of the procedure, possible alternative methods of treatment, (including, Physical therapy, oral pain medication, rest, surgery) have been explained to me. I **may** choose not to have the procedure.
*If any unforeseen condition arises in the course of the procedure calling for in her judgment for procedures in addition to or different from those now contemplated, I further request and authorize her to do whatever she deems advisable.
*I certify that I have read and fully understand the above consent to the procedure that the explanations there- referred to were made. The risks involved and the possibility of complications have been fully explained to me. I acknowledge that no guarantee or assurances have been made as to the results that may be obtained.
***I understand that X-ray is being used to guide the proper needle placement and that I am not pregnant**
ASA status: I II III Airway: MP Class: I II III IV

I consent to sedation under the direction of Dr. Bhambhani. _____(initial)

Patient/Authorized Person Signature Brenda Rozek Date 31 Aug 12

Physician Signature _____

EXHIBIT 1 tabbies

Millhausen, John 8/24/2012 - 4058 Ritu T. Bhambhani MD

Box Hill Surgery Center
100 Walter Ward Blvd Unit 300, Abingdon, MD 21009

INFORMED CONSENT FOR PROCEDURE

ALLERGIES: No known medication allergies.

I hereby authorize Dr. Bhambhani to perform ~~upon me,~~
Cervical/Thoracic/Lumbar/Caudal **Epidural Steroid Injection**
Selective Nerve Root Block B/L R L L1 L2 L3 L4 L5 S1
Facet Medial Branch Nerve Blocks B/L R L L2-3 L3-4 L4-5 L5- S1
B/L R L C3-4, 4-5, 5-6, 6-7, 7-T1
Radio-frequency ablation Medial Branch Nerves B/L R L L2-3 L3-4 L4-5 L5-SI
Sacro-Iliac joint injection B/L R L

The diagnosis requiring this procedure is Back/Neck/Leg/Arm pain. B/L
The nature of this procedure is to place a needle between or along the bones of my back or neck and inject medicine to reduce the swelling, inflammation and irritation around the nerves in an attempt to reduce/relieve my pain.

Material Risks of the Procedure:

As a result of the procedure being performed, there is the risk of:
INCREASED PAIN, LOSS OF BLOOD, SCARRING, INFECTION, ORGAN DAMAGE, ALLERGIC REACTION TO MEDICATIONS USED, SIDE EFFECTS FROM MEDICATIONS USED (fluid retention, congestive heart failure, rash, malaise, cramps), NERVE DAMAGE, NUMBNESS, TINGLING, HEADACHE, FAILURE TO WORK AS PLANNED.

*The nature and purpose of the procedure, possible alternative methods of treatment, (including, Physical therapy, oral pain medication, rest, surgery) have been explained to me. I **may** choose not to have the procedure.

*If any unforeseen condition arises in the course of the procedure calling for in her judgment for procedures in addition to or different from those now contemplated, I further request and authorize her to do whatever she deems advisable.

*I certify that I have read and fully understand the above consent to the procedure that the explanations there- referred to were made. The risks involved and the possibility of complications have been fully explained to me. I acknowledge that no guarantee or assurances have been made as to the results that may be obtained.

***I understand that X-ray is being used to guide the proper needle placement and that I am not pregnant**

ASA status: I II III Airway: MP Class: I II III IV

I consent to sedation under the direction of Dr. Bhambhani. _____(initial)

Patient/Authorized Person Signature John Millhausen Date 8-24-12

Physician Signature _____

Page: 3

Torbeck, Linda 1/8/2010 - 886 Ritu T. Bhambhani MD

Ritu T. Bhambhani, MD
100 Walker Ward Blvd Unit 300, Abdon, MD 21009

INFORMED CONSENT FOR PROCEDURE

ALLERGIES: Penicillin : hives, difficulty breathing, **Aspirin** : difficulty breathing, hives.

I hereby authorize Dr. Bhambhani to perform upon me,

Cervical/Thoracic/Lumbar/Caudal **Epidural Steroid Injection**
Selective Nerve Root Block B/L R L L1 L2 L3 L4 L5 S1
Facet Medial Branch Nerve Blocks B/L R L L2-3 L3-4 L4-5 L5- S1
B/L R L C3-4, 4-5, 5-6, 6-7, 7-T1
Radio-frequency ablation Medial Branch Nerves B/L R L L2-3 L3-4 L4-5 L5-SI
Sacro-Iliac joint injection B/L R L

The diagnosis requiring this procedure is Back/Neck/Leg/Arm pain.
The nature of this procedure is to place a needle between or along the bones of my back or neck and inject medicine to reduce the swelling, inflammation and irritation around the nerves in an attempt to reduce/relieve my pain.

Material Risks of the Procedure:
As a result of the procedure being performed, there is the risk of:
INCREASED PAIN, LOSS OF BLOOD, SCARRING, INFECTION, ORGAN DAMAGE, ALLERGIC REACTION TO MEDICATIONS USED, SIDE EFFECTS FROM MEDICATIONS USED (fluid retention, congestive heart failure, rash, malaise, cramps), NERVE DAMAGE, NUMBNESS, TINGLING, HEADACHE, FAILURE TO WORK AS PLANNED.
*The nature and purpose of the procedure, possible alternative methods of treatment, (including, Physical therapy, oral pain medication, rest, surgery) have been explained to me. I **may** choose not to have the procedure.
*If any unforeseen condition arises in the course of the procedure calling for in her judgment for procedures in addition to or different from those now contemplated, I further request and authorize her to do whatever she deems advisable.
*I certify that I have read and fully understand the above consent to the procedure that the explanations there- referred to were made. The risks involved and the possibility of complications have been fully explained to me. I acknowledge that no guarantee or assurances have been made as to the results that may be obtained.
***I understand that X-ray is being used to guide the proper needle placement and that I am not pregnant**
ASA status: I II III Airway: MP Class: I II III IV

I consent to sedation under the direction of Dr. Bhambhani. _____(initial)

Patient/Authorized Person Signature Linda J Torbeck Date 1/8/10

Physician Signature _____

Kashi, Bahman 9/5/2012 - 4119 Ritu T. Bhambhani MD

Box Hill Surgery Center
100 Walter Ward Blvd Unit 300, Abingdon, MD 21009

INFORMED CONSENT FOR PROCEDURE

ALLERGIES: Iodine : hives, rash.

I hereby authorize Dr. Bhambhani to perform upon me,
Cervical/Thoracic/Lumbar/Caudal **Epidural Steroid Injection**
Selective Nerve Root Block B/L R L L1 L2 L3 L4 L5 S1
Facet Medial Branch Nerve Blocks B/L R L L2-3 L3-4 L4-5 L5- S1
B/L R L C3-4, 4-5, 5-6, 6-7, 7-T1
Radio-frequency ablation Medial Branch Nerves B/L R L L2-3 L3-4 L4-5 L5-SI
Sacro-Iliac joint injection B/L R L

The diagnosis requiring this procedure is Back/Neck/Leg/Arm pain.
The nature of this procedure is to place a needle between or along the bones of my back or neck and inject medicine to reduce the swelling, inflammation and irritation around the nerves in an attempt to reduce/relieve my pain.

Material Risks of the Procedure:
As a result of the procedure being performed, there is the risk of:
INCREASED PAIN, LOSS OF BLOOD, SCARRING, INFECTION, ORGAN DAMAGE, ALLERGIC REACTION TO MEDICATIONS USED, SIDE EFFECTS FROM MEDICATIONS USED (fluid retention, congestive heart failure, rash, malaise, cramps), NERVE DAMAGE, NUMBNESS, TINGLING, HEADACHE, FAILURE TO WORK AS PLANNED.

*The nature and purpose of the procedure, possible alternative methods of treatment, (including, Physical therapy, oral pain medication, rest, surgery) have been explained to me. I **may** choose not to have the procedure.

*If any unforeseen condition arises in the course of the procedure calling for in her judgment for procedures in addition to or different from those now contemplated, I further request and authorize her to do whatever she deems advisable.

*I certify that I have read and fully understand the above consent to the procedure that the explanations there- referred to were made. The risks involved and the possibility of complications have been fully explained to me. I acknowledge that no guarantee or assurances have been made as to the results that may be obtained.

***I understand that X-ray is being used to guide the proper needle placement and that I am not pregnant**

ASA status: I II III Airway: MP Class: I II III IV

I consent to sedation under the direction of Dr. Bhambhani. _____(initial)

Patient/Authorized Person Signature _____ Date 9/5/2012

Physician Signature _____

Young, Edna 6/13/2012 - 3857 Ritu T. Bhambhani MD

Box Hill Surgery Center
100 Walter Ward Blvd Unit 300, Abingdon, MD 21009

INFORMED CONSENT FOR PROCEDURE

ALLERGIES: clindomycin, Cipro.

I hereby authorize Dr. Bhambhani to perform upon me,

Cervical/Thoracic/Lumbar/~~Caudal Epidural Steroid Injection~~
Selective Nerve Root Block B/L R L L1 L2 L3 L4 L5 S1
Facet Medial Branch Nerve Blocks B/L R L L2-3 ~~L3-4~~ L4-5 L5- S1
B/L R L C3-4, 4-5, 5-6, 6-7, 7-T1
Radio-frequency ablation Medial Branch Nerves B/L R L L2-3 L3-4 L4-5 L5-SI
Sacro-Iliac joint injection B/L R L

The diagnosis requiring this procedure is Back/Neck/Leg/Arm pain.
The nature of this procedure is to place a needle between or along the bones of my back or neck and inject medicine to reduce the swelling, inflammation and irritation around the nerves in an attempt to reduce/relieve my pain.

Material Risks of the Procedure:
As a result of the procedure being performed, there is the risk of:
INCREASED PAIN, LOSS OF BLOOD, SCARRING, INFECTION, ORGAN DAMAGE, ALLERGIC REACTION TO MEDICATIONS USED, SIDE EFFECTS FROM MEDICATIONS USED (fluid retention, congestive heart failure, rash, malaise, cramps), NERVE DAMAGE, NUMBNESS, TINGLING, HEADACHE, FAILURE TO WORK AS PLANNED.
*The nature and purpose of the procedure, possible alternative methods of treatment, (including, Physical therapy, oral pain medication, rest, surgery) have been explained to me. I **may** choose not to have the procedure.
*If any unforeseen condition arises in the course of the procedure calling for in her judgment for procedures in addition to or different from those now contemplated, I further request and authorize her to do whatever she deems advisable.
*I certify that I have read and fully understand the above consent to the procedure that the explanations there- referred to were made. The risks involved and the possibility of complications have been fully explained to me. I acknowledge that no guarantee or assurances have been made as to the results that may be obtained.
***I understand that X-ray is being used to guide the proper needle placement and that I am not pregnant**
ASA status: I II III Airway: MP Class: I II III IV

I consent to sedation under the direction of Dr. Bhambhani. EY (initial)

Patient/Authorized Person Signature Edna Young Date 6-13-12

Physician Signature

Dreisch, Belinda 5/18/2012 - 3083 Ritu T. Bhambhani MD

Box Hill Surgery Center
100 Walter Ward Blvd Unit 300, Abingdon, MD 21009

INFORMED CONSENT FOR PROCEDURE

ALLERGIES: Penicillin : swelling.

I hereby authorize Dr. Bhambhani to perform upon me,

Cervical/Thoracic/Lumbar/Caudal **Epidural Steroid Injection**
Selective Nerve Root Block B/L R L L1 L2 L3 L4 L5 S1
Facet Medial Branch Nerve Blocks B/L R L L2-3 L3-4 L4-5 L5- S1
B/L R L C3-4, 4-5, 5-6, 6-7, 7-T1
Radio-frequency ablation Medial Branch Nerves B/L R L L2-3 L3-4 L4-5 L5-SI
Sacro-Iliac joint injection B/L R L

The diagnosis requiring this procedure is Back/Neck/Leg/Arm pain.
The nature of this procedure is to place a needle between or along the bones of my back or neck and inject medicine to reduce the swelling, inflammation and irritation around the nerves in an attempt to reduce/relieve my pain.

Material Risks of the Procedure:
As a result of the procedure being performed, there is the risk of:
INCREASED PAIN, LOSS OF BLOOD, SCARRING, INFECTION, ORGAN DAMAGE, ALLERGIC REACTION TO MEDICATIONS USED, SIDE EFFECTS FROM MEDICATIONS USED (fluid retention, congestive heart failure, rash, malaise, cramps), NERVE DAMAGE, NUMBNESS, TINGLING, HEADACHE, FAILURE TO WORK AS PLANNED.

*The nature and purpose of the procedure, possible alternative methods of treatment, (including, Physical therapy, oral pain medication, rest, surgery) have been explained to me. I **may** choose not to have the procedure.

*If any unforeseen condition arises in the course of the procedure calling for in her judgment for procedures in addition to or different from those now contemplated, I further request and authorize her to do whatever she deems advisable.

*I certify that I have read and fully understand the above consent to the procedure that the explanations there- referred to were made. The risks involved and the possibility of complications have been fully explained to me. I acknowledge that no guarantee or assurances have been made as to the results that may be obtained.

***I understand that X-ray is being used to guide the proper needle placement and that I am not pregnant**

ASA status: I II III Airway: MP Class: I II III IV

I consent to sedation under the direction of Dr. Bhambhani. BD (initial)

Patient/Authorized Person Signature Belinda Dreisch Date 5-18-12

Physician Signature

Davis, Teresa 7/20/2012 - BH3913 Ritu T. Bhambhani MD

Box Hill Surgery Center
100 Walter Ward Blvd Unit 300, Abingdon, MD 21009

INFORMED CONSENT FOR PROCEDURE

ALLERGIES: No known medication allergies.

I hereby authorize Dr. Bhambhani to perform upon me,

Cervical/Thoracic/Lumbar/Caudal **Epidural Steroid Injection**
Selective Nerve Root Block B/L R L L1 L2 L3 L4 L5 S1
Facet Medial Branch Nerve Blocks B/L R L L2-3 L3-4 L4-5 L5- S1
B/L R L C3-4 4-5, 5-6, 6-7, 7-T1
Radio-frequency ablation Medial Branch Nerves B/L R L L2-3 L3-4 L4-5 L5-S1
Sacro-Iliac joint injection B/L R L

The diagnosis requiring this procedure is Back/Neck/Leg/Arm pain.
The nature of this procedure is to place a needle between or along the bones of my back or neck and inject medicine to reduce the swelling, inflammation and irritation around the nerves in an attempt to reduce/relieve my pain.

Material Risks of the Procedure:
As a result of the procedure being performed, there is the risk of:
INCREASED PAIN, LOSS OF BLOOD, SCARRING, INFECTION, ORGAN DAMAGE, ALLERGIC REACTION TO MEDICATIONS USED, SIDE EFFECTS FROM MEDICATIONS USED (fluid retention, congestive heart failure, rash, malaise, cramps), NERVE DAMAGE, NUMBNESS, TINGLING, HEADACHE, FAILURE TO WORK AS PLANNED.
*The nature and purpose of the procedure, possible alternative methods of treatment, (including, Physical therapy, oral pain medication, rest, surgery) have been explained to me. I **may** choose not to have the procedure.
*If any unforeseen condition arises in the course of the procedure calling for in her judgment for procedures in addition to or different from those now contemplated, I further request and authorize her to do whatever she deems advisable.
*I certify that I have read and fully understand the above consent to the procedure that the explanations there- referred to were made. The risks involved and the possibility of complications have been fully explained to me. I acknowledge that no guarantee or assurances have been made as to the results that may be obtained.
***I understand that X-ray is being used to guide the proper needle placement and that I am not pregnant**
ASA status: I II III Airway: MP Class: I II III IV

I consent to sedation under the direction of Dr. Bhambhani. TD (initial)

Patient/Authorized Person Signature Teresa Davis Date 20 July 2012

Physician Signature

Box Hill Surgery Center
100 Walter Ward Blvd Unit 300, Abingdon, MD 21009

INFORMED CONSENT FOR PROCEDURE

ALLERGIES: No known medication allergies.

I hereby authorize Dr. Bhambhani to perform upon me,

Cervical/Thoracic/Lumbar/Caudal **Epidural Steroid Injection**
Selective Nerve Root Block B/L R (L) L1 L2 L3 L4 (L5) S1
Facet Medial Branch Nerve Blocks B/L R L L2-3 L3-4 L4-5 L5- S1
B/L R L C3-4, 4-5, 5-6, 6-7, 7-T1
Radio-frequency ablation Medial Branch Nerves B/L R L L2-3 L3-4 L4-5 L5-SI
Sacro-Iliac joint injection B/L R L

The diagnosis requiring this procedure is (Back/Neck/Leg/Arm pain).
The nature of this procedure is to place a needle between or along the bones of my back or neck and inject medicine to reduce the swelling, inflammation and irritation around the nerves in an attempt to reduce/relieve my pain.

Material Risks of the Procedure:
As a result of the procedure being performed, there is the risk of:
INCREASED PAIN, LOSS OF BLOOD, SCARRING, INFECTION, ORGAN DAMAGE, ALLERGIC REACTION TO MEDICATIONS USED, SIDE EFFECTS FROM MEDICATIONS USED (fluid retention, congestive heart failure, rash, malaise, cramps), NERVE DAMAGE, NUMBNESS, TINGLING, HEADACHE, FAILURE TO WORK AS PLANNED.
*The nature and purpose of the procedure, possible alternative methods of treatment, (including, Physical therapy, oral pain medication, rest, surgery) have been explained to me. I **may** choose not to have the procedure.
*If any unforeseen condition arises in the course of the procedure calling for in her judgment for procedures in addition to or different from those now contemplated, I further request and authorize her to do whatever she deems advisable.
*I certify that I have read and fully understand the above consent to the procedure that the explanations there- referred to were made. The risks involved and the possibility of complications have been fully explained to me. I acknowledge that no guarantee or assurances have been made as to the results that may be obtained.
***I understand that X-ray is being used to guide the proper needle placement and that I am not pregnant**
ASA status: I II III Airway: MP Class: I II III IV

I consent to sedation under the direction of Dr. Bhambhani. AF (initial)

Patient/Authorized Person Signature Angela Farthing Date 6/29/12

Physician Signature